2014-2016 NAS Task and EPA Controlled Exposure Studies

To understand the risks posed by environmental pollution, the Environmental Protection Agency (EPA) and other organizations conduct research on the health effects of pollutants. For example, under the Clean Air Act, EPA is authorized to conduct research on the short-term and long-term effects of air pollutants on human health, including epidemiological, clinical, laboratory, and field studies as necessary. The Clean Air Act also requires that EPA establish and regularly review the National Ambient Air Quality Standards (NAAQS) for the six criteria air pollutants which are commonly found air pollutants that are considered harmful to public health and the environment. Research studies are used as the scientific foundation for setting and reviewing air quality standards.

As part of its air pollution research program, EPA conducts controlled exposure studies, during which human subjects are intentionally exposed to pollutants, such as ozone or particulate matter, under carefully controlled conditions. The levels of pollutants used in these studies are similar to what the American public experiences in a city with poor air quality, if they were driving down a busy freeway or waiting at a bus stop. This type of research study provides specific information on human biological responses to air pollution exposures which cannot be obtained by any other research methods. Similar studies are conducted at universities, often funded by the National Institutes of Health. Results from these studies are evaluated in combination with results from other research to provide a more complete understanding of the health effects of the pollutants. This refined understanding ultimately helps inform EPA's decisions to protect public health.

Studies involving human subjects are governed by federal regulations. The Federal Policy for the Protection of Human Subjects, the "Common Rule," was published in 1991 and codified in separate regulations by 18 Federal departments and agencies, including EPA.

EPA's approval process guidelines exceed what is generally accepted and required by universities, industry, and other government agencies. In those organizations, human subjects research is often proposed by an investigator, reviewed by a supervisor, and finally, reviewed by an Institutional Review Board (IRB). Research conducted or supported by EPA goes through those steps, but there are also several additional levels of oversight. For example, controlled human exposure studies often undergo up to 13 levels of both internal and external review. These additional reviews ensure that risks to subjects are minimized and that all study procedures conform to best practices in science and ethics.

EPA's exposure studies were reviewed in 2014 by the Office of the Inspector General (OIG) and found to be in compliance with all regulations and policies. The OIG made suggestions for improvements, and EPA has incorporated those recommendations. In 2014, EPA has commissioned a study of the National Academies of Sciences (NAS) to make recommendations

on very specific aspects of our research. The committee has been charged to look at the complicated issues of risk and benefit in our controlled human exposure studies. While this was not required, it reflects EPA's commitment to continuous quality improvement and upholding the highest standards in research. The NAS has followed its standard process which is not controlled by EPA. The NAS report is expected in September of 2016. Information about the current status of the project is available on the public website of the NAS.